

## II. REMARKS

### A. Introduction

Applicants submit this Response in a bona fide attempt to (i) advance the prosecution of this case, (ii) answer each and every ground of objection and rejection as set forth by the Examiner, (iii) place the claims in a condition for allowance, and (iv) place the case in better condition for consideration on appeal. Applicants respectfully request reexamination and reconsideration of the above referenced patent application in view of this Response.

Claims 1, 6, 11, 15 and 23-27 are currently pending in the application. As indicated above, Claims 1, 6 and 25 have been amended.

As set forth in detail in the specification and discussed with the Examiner, Applicants' invention is distinguished from the prior art by, among other things, the collection and transmission of naturally generated waveforms having instructions embodied therein that are operative in the regulation of body organs. See, e.g.,

The [waveform] signal is of a direct current nature and has many coded modulations that provide directions or instructions to the receptor organ or system receiving it. (p. 10, ll. 15-16)

\* \* \*

Key organ systems such as cardiovascular, respiratory, digestive and others decode these [signaling waveforms] and modulate or fine-tune themselves in response to those instructions. (p. 7, ll. 17-19)

Independent Claims 1, 6 and 25 have accordingly been amended to provide that the collected and transmitted waveforms include "instructions that are operative in the regulation of a function associated with a body organ".

Applicants thus respectfully submit that the noted claim amendment merely make explicit that which was (and is) disclosed in the original disclosure. The amendment thus adds nothing that would not be reasonably apparent to a person of ordinary skill in the art to which the invention pertains.

## **B. Response to Rejections**

### **1. 35 U.S.C. § 112**

The Examiner has rejected Claims 1 and 23-27 under 35 U.S.C. § 112, first paragraph, “as failing to comply with the written description requirement.” The Examiner contends:

The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of the limitations of collecting a plurality of waveforms “from an autonomic nervous network in a body” (claim 1), wherein the autonomic nervous network comprises the “vagus nerve” and/or “hypoglossal nerve bundle” (claims 1 and 25), in combination with the other elements or steps were not previously described in the specification to reasonably convey necessity for their inclusion into the claimed subject matter.

Contrary to the Examiner’s contention, Applicants respectfully submit that the noted claim limitations are described in the specification, whereby one having ordinary skill in the art could not reasonably dispute that the Applicants had full possession of the invention(s) at the time the application was filed. On page 3, lines 17-18 and 23-24, and page 4, lines 1-2, the specification provides:

Within the central nervous system is the autonomic nervous system (ANS) which carries all efferent impulses except for the motor innervation of skeletal muscles.

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The nervous system is constructed of nerve cells called neurons which have supporting cells called glia. Neurons are electrically excitable and provide a method whereby instructions are carried from the brain to modulate critical functions.

On page 7, line 24 through page 8, line 6, the specification further provides:

The invention focuses on the electrical signals transported by the vagus accessory and hypoglossal nerve bundles, including efferent fibers. ... The hypoglossal and accessory nerves ... emerge from the medulla oblongata and are interlaced with the vagus to harmoniously accomplish basic life support. The signals travel on the surface of the vagus nerve....

Applicants therefore respectfully request that the rejections under 35 U.S.C. § 112 be withdrawn.

## 2. 35 U.S.C. §102

The Examiner has also rejected Claims 1, 6, 10-11 and 15 under 35 U.S.C. §102(b) “as being anticipated by Kennedy (U.S. 4,852,573)”. The Examiner contends, *inter alia*:

Kennedy teaches a system and method for stimulating and regulating body organ function. The method includes collecting waveforms from the brain or nervous system that are representative of waveforms naturally occurring within a body from a body; at least temporarily storing the collected waveforms in a storage medium (33); and transmitting a first waveform signal including at least a second waveform that substantially corresponds to one or more collected waveforms to the nervous system to stimulate organ function. The system includes a source of collected waveforms (33); means for transmitting (22, 31) at least one of the collected waveforms to a body organ; and means for applying (30, 58) the transmitted waveforms to the body organ. Recording electrodes (30, 58) are placed on the body to collect the waveforms in analog form and transmit the waveforms to the storage medium.

It is well established that a rejection for anticipation under § 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. *See In re Paulsen*, 30 F.3d 1475, 1478-79, 31 U.S.P.Q. 2d 1671, 1673 (Fed. Cir. 1994); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q. 2d 1001 (Fed. Cir.1991). *See also American Permahedge, Inc. v. Barcana, Inc.*, 857 F. Supp. 308, 32 U.S.P.Q. 2d 1801, 1807-08 (S.D. NY 1994) (“Prior art anticipates an invention ... if a single prior art reference contains each and every element of the patent at issue, operating in the same fashion to perform the identical function as the patent product. ... Thus, any degree of physical difference between the patented product and the prior art, *no matter how slight*, defeats the claim of anticipation.”); *Transco Ex parte Levy*, 17 U.S.P.Q. 2d 1461, 1462 (Bd. Pat. App. & Int’l 1990) (“[I]t is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference”).

Applicants respectfully submit that the claimed invention is **not** anticipated by Kennedy. As set forth in detail below, Kennedy does **not** disclose or even suggest the seminal limitations of the claimed invention.

Although Kennedy discloses an implantable electrode that can be employed to collect or transmit signals to the body, Kennedy **does not** disclose or even suggest (i) storing a collected plurality of naturally generated waveforms, having instructions embodied therein that are

operative in the regulation of a function associated with at least one body organ, in a storage medium according to the function regulated by the instructions or (ii) selecting a waveform having at least a first instruction that is operative in the regulation of the body organ function from the collected plurality of waveforms or (iii) transmitting the selected waveform to the body organ to regulate the body organ function (i.e. Claim 1).

Kennedy also **does not** disclose or even suggest or (i) a source of naturally generated waveforms that include instructions that are operative in the regulation of a function associated with at least one body organ or (ii) means for selecting a naturally generated waveform having at least a first instruction that is operative in the regulation of the body organ function from the source of naturally generated waveforms (i.e. Claim 6).

Indeed, ***Kennedy is devoid of any reference to the instructions that are embodied in waveforms that are transmitted to modulate functions of body organs.***

Applicants thus submit that Kennedy does not disclose “each and every limitation of the claimed invention.” Applicants accordingly respectfully request that the rejections under 35 U.S.C. § 102(b) be withdrawn.

### **3. 35 U.S.C. §103**

The Examiner has also rejected Claims 6, 11 and 15 under 35 U.S.C. §102(e) “as being anticipated by or, in the alternative, under 35 U.S.C § 103(a) as obvious over Kieval, et al.” The Examiner contends:

Kieval, et al. discloses a device to “be used to increase or decrease blood pressure, sympathetic nervous system activity and neurohormonal activity, as needed to minimize deleterious effects on the heart, vasculature and other organs and tissues” (col. 21, lines 11-14) by activating the baroreceptors. Kieval, et al. also discloses in column 21, lines 15-16 that “the baroreceptor activation devices described previously may also be used to provide antiarrhythmic effects”. As seen in figure 3, “the control system 60 generates a control signal as a function of the received sensor signal. The control signal activates, deactivates or otherwise modulates the baroreceptor activation device 70. Typically, activation of the device 70 results in activation of the baroreceptors 30” (col. 9, lines 33-37). The examiner considers the control system to be the storage area where the signals are generated.

In the alternative, Kieval, et al. discloses the claimed invention except for the memory to the store waveforms. It would have

been obvious to one having ordinary skill in the art at the time the invention was made to modify the control system and method as taught by Kieval, et al. with a memory to store waveforms since it was known in the art that storing and recording data can provide physicians with information on the status of their patient.

It is well established that in determining what is and what is not obvious under § 103, all properties and advantages not in the prior art must be considered. See *In re Wright*, 848 F.2d 1216, 6 U.S.P.Q. 2d 1959, 1962 (Fed. Cir. 1988) (“Factors including unexpected results, new features, solution of a different problem, novel properties, are all considerations in the determination of obviousness in terms of 35 U.S.C. § 103”). Indeed, it is the invention as a whole, including distinct functions that must be considered in obviousness determinations.

It is further well established that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or motivation to do so found either in the prior art or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 U.S.P.Q. 2d 1941 (Fed. Cir. 1992). See also *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 922 (Fed. Cir. 1984).

*Kieval, et al. is similarly devoid of any reference to the instructions that are embodied in naturally generated waveforms.* Kieval, et al. thus **does not** teach or even suggest (i) a source of naturally generated waveforms that include instructions that are operative in the regulation of a function associated with at least one body organ or (ii) means for selecting a naturally generated waveform having at least a first instruction that is operative in the regulation of the body organ function from the source of naturally generated waveforms (i.e. Claim 6).

Kieval, et al. merely teaches (i) the generation of “continuous control signals, periodic control signals, episodic control signals, or combinations thereof” that are specifically and solely tailored to activate a baroreceptor activation device, which, in turn, activates and/or controls baroreceptors; and (ii) the direct transmission of the “user generated” control signals to the baroreceptor activation device.

Applicants accordingly respectfully submit that the invention embodied in Claims 6, 11 and 15 are unobvious in view of Kieval, et al. Applicants accordingly respectfully request that the rejections under 35 U.S.C. § 103 be withdrawn.

#### 4. Double Patenting

The Examiner has additionally rejected Claims 1, 6, 10-11 and 15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Pat. No. 6,633,779. The Examiner contends:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims meet the limitations of the transmitting or broadcasting waveforms to an organ to affect the functioning of an organ in the body.

Applicants are accordingly submitting herewith a Terminal Disclaimer for U.S. Pat. No. 6,633,779 to overcome the double patenting rejection.

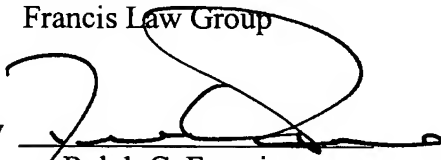
#### III. CONCLUSION

Applicants having answered each and every ground of objection and rejection as set forth by the Examiner, and having added no new matter, believe that this response clearly overcomes the references of record, and now submit that Claims 1, 6, 11, 15 and 23-27 in the above referenced patent application are in condition for allowance and the same is respectfully solicited.

If the Examiner has any further questions or comments, Applicants invite the Examiner to contact their Attorneys of record at the telephone number below to expedite prosecution of the application.

Respectfully submitted,  
Francis Law Group

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## APPENDIX A

FOR: Method to Record, Store and Broadcast  
Specific Brain Waveforms to Modulate  
Body Organ Functioning